K123938

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This 510(k) summary is being submitted in accordance with 21 CFR § 807.92.

General Information

Establishment

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Contact Person

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Device Name

Software *syngo* MR B19 for MAGNETOM Avanto, Espree, Symphony A Tim System, Trio A Tim System, and Verio

CFR Code

21 CFR § 892.1000

Classification

Class II

Product Codes

LNH, LNI, MOS

Classification Name

Magnetic Resonance Diagnostic Device, MR Spectroscopy, MR Coils

Information Supporting Substantial Equivalence

DEVICE DESCRIPTION

Software *syngo* MR B19 is a new software version for five Siemens MR systems: MAGNETOM Avanto (1.5T), Espree (1.5T), Symphony A Tim System (1.5T), Trio A Tim System (3T), and Verio (3T). Systems that are already in clinical use and at customer sites (referred to as "field upgrades" throughout the rest of the submission) can be upgraded to this software version; some of the five MAGNETOM systems will be manufactured (referred to as "ex-factory systems" throughout the rest of this submission) with this software version (please see table below).

This new software version includes new software sequences, coils and other hardware for the five MAGNETOM systems. While some new features (hardware and software) are only available for certain systems (of the five listed), the basic *syngo* MR B19 software can run on each of the five MAGNETOM systems. Therefore, while five MAGNETOM systems are mentioned throughout this submission, the software version is the subject of this 510(k).

Summary of Features New with Software *syngo* MR B19 compared to predicate *syngo* MR B17:

Hardware

- Magnet: New shim sequence
- New coils:
  - 4 Channel Special Purpose Coil
  - Sentinelle Breast 16ch Coil
  - Sentinelle Breast 8ch Coil
  - Sentinelle Endo Array coil

Software

- New or modified sequences for all five systems for body, neurological, abdominal, and orthopedic imaging.
- New software for all five systems:
  - RTC (Rich Thin Client) hosting

The above features have been previously cleared in the predicate, *syngo* MR D13A on November 5, 2012.

INTENDED USE

The MAGNETOM systems Avanto, Espree, Symphony A Tim System, Trio A Tim System, and Verio with software *syngo* MR B19 are indicated for use as magnetic resonance diagnostic devices (MRDD) that produce transverse, sagittal, coronal and oblique cross-sectional images, spectroscopic images and/or spectra, and that display the internal structure and/or function of the head, body, or extremities.

Other physical parameters derived from the images and/or spectra may also be produced. Depending on the region of interest, contrast agents may be used. These images and/or spectra and the physical parameters derived from the images and/or spectra, when interpreted by a trained physician, yield information that may assist in diagnosis.

The MAGNETOM systems may also be used for imaging during interventional procedures when performed with MR compatible devices such as in-room display and MR-safe biopsy needles.

NONCLINICAL TESTS

Performance testing such as SNR, image uniformity, and heating were conducted on the subject device. Additionally, all software features were verified and validated.

The results from each set of tests demonstrate that the device performs as intended and is thus substantially equivalent to the predicate devices to which it has been compared.

CLINICAL TESTS

There were not any clinical tests conducted to support the subject device and the substantial equivalence argument, however clinical images are provided to support the new coils as well as the new and modified software features of the subject device.

SUBSTANTIAL EQUIVALENCE

Software *syngo* MR B19 for MAGNETOM Avanto, Espree, Symphony A Tim System, Trio A Tim System, and Verio is substantially equivalent to the following predicate devices:

Table 1: Predicate device for *syngo* MR B19 for MAGNETOM Avanto, Espree, Symphony A Tim System, Trio A Tim System, and Verio

Predicate Device Name	FDA Clearance Number	FDA Clearance Date	Main Product Code
MAGNETOM Avanto, Espree, Symphony A Tim System, Trio A Tim System, and Verio with *syngo*® MR B17	K082427	November 7, 2008	LNH

Predicate Device Name	FDA Clearance Number	FDA Clearance Date	Main Product Code
MAGNETOM Aera, Skyra, Avanto, and Verio with *syngo*® MR D13A	K121434	November 5, 2012	LNH

SAFETY AND EFFECTIVENESS

The device labeling contains instructions for use and any necessary cautions and warnings to provide for safe and effective use of the device.

Risk Management is ensured via a risk analysis in compliance with ISO 14971:2007 to identify and provide mitigation to potential hazards beginning early in the design cycle and continuing throughout the development of the product. Siemens Medical Solutions USA, Inc. and Siemens AG adhere to recognized and established industry standards, such as the IEC 60601-1 series, to minimize electrical and mechanical hazards.

The MAGNETOM systems Avanto, Espree, Symphony A Tim System, Trio A Tim System, and Verio with software *syngo* MR B19 conform to the applicable FDA recognized and international IEC, ISO and NEMA standards with regards to performance and safety as recommended by the respective MR FDA Guidance Document.

SUBSTANTIAL EQUIVALENCE CONCLUSION

There are no changes to the Indications for Use for the subject device, compared to that of the predicate MAGNETOM systems with software *syngo* MR B17 and *syngo* MR D13A.

While the new hardware and software provides the user with additional capabilities compared to the five subject MAGNETOM systems with the previous software version *syngo* MR B17, it has the same technological characteristics as that of the predicate devices. The new features from *syngo* MR D13A made available for the new software version, *syngo* MR B19, the subject of this premarket notification make the systems and software more user-friendly. These modifications improve the user's workflow and reduce the complexity of certain imaging procedures; providing additional output, information, and options to the user; and reduce image artifacts.

The differences between the subject device and the predicate devices, which include the aforementioned new sequences, coils, and hardware, give the systems the same (compared to *syngo* MR D13A) or enhanced (compared to *syngo* MR B17) capabilities with respect to the predicate devices, but have the same technological characteristics as the predicate devices, are similar to the functionalities of the predicate devices, and do not introduce any new issues of safety or effectiveness. Therefore, Siemens believes that the subject device, software version *syngo* MR B19 for MAGNETOM Avanto, Espree, Symphony A Tim System, Trio A Tim System, and Verio, is substantially equivalent to the predicate devices, *syngo* MR B17 and *syngo* MR D13A.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Ms. Nadia Sookdeo
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Mail Code D02
MALVERN PA 19355

February 12, 2013

Re: K123938
Trade/Device Name: Syngo MR B19 MAGNETOM Avanto (1.5T), Espree (1.5T), Symphony A Tim System (1.5T), Trio A Tim System (3T), and Verio (3T) MR systems
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: December 19, 2012
Received: December 20, 2012

Dear Ms. Sookdeo,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Michael D. O'Hara

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known) K123938

Device Name: **Software *syngo* MR B19 for MAGNETOM Avanto, Espree, Symphony A Tim System, Trio A Tim System, and Verio**

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Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Michael D. O'Hara

(Division Sign Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510(k) K123938